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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,834	03/20/2006	Steffen Goletz	00056-0001-001	7472

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Fanelli Strain & Haag PLLC
1455 Pennsylvania Ave., N.W., suite 400
Washington, DC 20004

EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,834	GOLETZ ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *76,79 and 81-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *76* is/are allowed.

6)☒ Claim(s) *79 and 81-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/10/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 74, 77, 78 and 80 have been canceled. Claims 76 and 79 have been amended. Claims 76, 79, 81-84 are pending and under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 79 and 81-84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1) a construct comprising the recombinant recognition molecule of claim 76 further comprising enzyme molecules, signal sequences, fluorescent dyes, toxin, one or more antibodies or antibody fragment with different antigen-binding specificity, cytolytic components, immunomodulators, immunoeffectors, chelating agents for radioactive labeling, radioisotopes or liposomes and 2) a method for the diagnosis, reduction therapy, follow-up or after care of a Core-1 positive tumor disease or a Core-1 positive metastasis comprising the administration of the recognition molecule comprising the CDRs of the recited amino acid sequences, wherein said recognition molecule specifically binds to the Core-1 antigen, does not reasonably provide enablement for 1) a construct comprising the recombinant recognition molecule of claim 76 further comprising interaction domains, domains for stabilization, catalytic antibodies, MHC I or II antigens, transmembrane domains, viruses and cells, or 2) the prophylaxis of a Core-1 positive tumor disease . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

(A) As drawn to prophylaxis of a Core-1 positive tumor disease

Claims 81-84 are drawn in part to the prophylaxis of a Core-1 positive tumor disease or a Core-1 positive metastasis. When given the broadest reasonable interpretation, the claims encompass the prevention of a de novo tumor in a non-experimental subject. In order for prophylaxis to be carried out the treatment with the claimed recognition molecule must be given before the Core-positive tumor actually occurs in the subject. The specification fails to teach the

positive identification of individual who will develop Core- positive tumor tumors in order to provide the recognition molecules to said individual before said tumors occur. further, the specification fails to teach the optimum time before tumor occurrence at which to administer the recognition molecule. Additionally, the recognition molecule when administered before the occurrence of a de novo tumor will not have tumor antigen with which to bind. Consequently, mechanisms such as ADCC, or other immune effects elicited from antigen-antibody binding will not be expected to occur. The specification has failed to address or provide guidance for these issues. Consequently, one of skill in the art would be subject to undue experimentation is order to carry out the claimed methods for prophylaxis of a Core-1 positive tumor.

(B) As drawn to a construct comprising the recognition molecule of claim 76 further comprising (1) interaction domains, (2) domains for stabilization, (3) catalytic antibodies, (4) MHC I or II antigens, (5) transmembrane domains, (6) viruses and/or (7) generic cells, and methods of treatment comprising the administration of said recognition molecule further comprising (1) interaction domains, (2) domains for stabilization, (3) catalytic antibodies, (4) MHC I or II antigens, (5) transmembrane domains, (6) viruses and/or (7) generic cells

Claim 79 is drawn in part to recognition molecule further comprising a "interaction domain" and/or a domain for stabilization. The specification provides no teaching as to what the "interaction" is in reference to or what the stability is in reference to, such as a mutant constant region leading to increased half life in circulation (Presta et al, U.S. 5,739,277, cited in a prior acion), or if the stabilization was some other type of stabilization.

Claim 79 is drawn in part to the recognition molecule further comprising a catalytic antibody. The specification has failed to teach a molecule which requires catalyisis in the context of the extracellular environment of a tumor as there is no evidence that the core-1 antigen undergoes endocytosis to the cytoplasm. Thus, without the target for the catalysis, one of skill in the art would be subject to undue experimentation in order to make and use the construct comprising catalytic antibodies (Hsieh et al, Science, 1993, vol. 260, pp. 337-339, cited in a prior acion).

Claim 79 is drawn in part to a recognition molecule further comprising a MHC class I or class II antigens. The specification provides no teachings as to how to use the transport of an empty MHC I or II receptor or peptides that bind in the context of the MHC targeted to a cancer

cell via the instant recognition molecules. T cell recognize peptides presented in the context of an MHC molecule on the surface of a cell. T cells exposed to peptides which are not presented by antigen presenting cells in the context of the MHC leads to T cell death (Matzinger, Annual Review in Immunology, 1994, Vol. 12, pp. 991-1045, page 998, lines 5-11 and page 1001, lines 8-16, cited in a prior acion). Thus, it is unclear how to use a construct comprising these antigens for inducing tumor reduction.

Claim 79 is drawn in part to a recognition molecule further comprising a transmembrane domain. The specification states that the fusion of an scFv with a transmembrane domain, such as that found in c-erbB2, PDGF receptor, human transferring record or human asaialglycoprotein receptor enable the expression for the binding molecules on the surface of the cells. The art teaches that the presence of the transmembrane domain allows for the stabilization of a protein in the cell membrane after transport through the cytoplasm the rather than secretion of said protein (Schneider et al, FEBS Lett, 2002, vol. 532, pp. 231-236, cited in a prior action). However, there is no objective evidence that the converse, insertion into the cell membrane after contact with the cell membrane from the extracellular milieu, would lead to insertion of the recognition molecule comprising the transmembrane domain into the cell surface.

Claim 79 is drawn in part to a recognition molecule further comprising a virus. The specification fails to teach how to use the recognition molecule when conjugated to a virus. There is no reasonable expectation that binding of the recognition molecule to a core 1 antigen on the surface of a target cell, wherein said recognition molecule is attached to a virus, will lead to internalization of said virus within the cell. The art teaches that cell surface receptors on hematopoietic cells more often undergo internalization in contrast to non-hematopoietic receptors because hematopoietic cells are more dependent on external growth factors. Thus, given a non-hematopoietic cell, there is no reasonable expectation that binding of a conjugated or fused recognition molecule when bound to a cell surface protein will result in internalization of the conjugated or fused moiety. Thus, without further objective evidence form the specification, one of skill in the art would conclude that the virus attached to the recognition molecule will remain external to the cell. Further, when given the broadest reasonable interpretation, the "virus" includes any killed and modulated pathogenic viruses. The specification fails to teach how the recombinant construct further comprising the broadly claimed virus would contribute to

the diagnosis, reduction, therapy, follow up or after care of a Core-1 positive tumor disease or a Core-1 metastasis.

Claim 79 is drawn in part to a recognition molecule further comprising a cell. When given the broadest reasonable interpretation, the term "cells" encompasses multitude of cells and are not limited to phagocytes, such as macrophage or dendritic cells. One of skill in the art would not know how to use the claimed construct comprising cells which are not phagocytic..

The specification fails to address or provide guidance for any of the above issues, Accordingly, one of skill in the art would be subject to undue experimentation in order to make and use the instant constructs.

All other rejections and objections as set forth or maintained in the prior Office action are withdrawn in light of applicant's amendments.

Claim 76 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu can be reached on (571)272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/

Primary Examiner, Art Unit 1643